130 (2) 08-1390

Supreme Court, U.S.
FILED
JAN 12 2009
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

ESTATE OF MARION LANDERS,
as represented by its executor, Richard Landers,
MARION A. DIXON, and MURIEL GRIGLEY, on
behalf of themselves and all others similarly
situated,

Petitioners,

v.

KATHLEEN SEBELIUS, Secretary of the
Department of Health and Human Services,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

BRIEF *AMICUS CURIAE* OF AARP IN SUPPORT OF PETITIONERS

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STATEMENT OF INTEREST[1]

AARP is a nonpartisan, nonprofit membership organization of nearly 40 million persons, age 50 or older, dedicated to addressing the needs and interests of older persons. AARP has a long history of advocating for its membership's access to affordable health care and for controlling costs without compromising quality. As many AARP members are Medicare enrollees, AARP supports their efforts to access health care provided under the program.

REASONS FOR GRANTING THE WRIT

Introduction

Medicare payment is only available for post hospitalization care in a skilled nursing facility (SNF) if the beneficiary has been an inpatient for not less than three consecutive days before discharge from a hospital and transfer to a nursing facility. 42 U.S.C. § 1395x(I) (2006); 42 C.F.R. § 409.30(a)(1) (2006). Inpatient is neither defined by statute nor regulation, but the Secretary of Health and Human Services has interpreted inpatient as requiring that

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[1] No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae*, its members, or its counsel made a monetary contribution to the preparation and submission of this brief. Counsel of record for all parties received notice at least 10 days prior to the due date of the *amicus curiae's* intention to file this brief. The parties have consented to the filing of this brief.

a patient be formally admitted to a hospital. Centers for Medicare & Medicaid Services (CMS), Department of Health & Human Services, Pub. No. 100-02, Medicare Benefit Policy Manual, ch.1, § 10 (45th rev. 2006) *available at* http://cms.hhs.gov/manuals/IOM/list/asp; *Landers v. Leavitt*, 545 F. 3d 98, 104 (2d Cir. 2008).

Medicine and the standards for patient care have changed since the creation of the Medicare program in 1965. Care that may have been provided during a three-day inpatient hospital stay in 1965 may now be provided during observation status, a status that did not exist then. Medicare beneficiaries who require acute hospitalization that involves a three-day stay, whether technically admitted as a hospital inpatient or merely held in observation status, should not be disqualified from receiving SNF coverage. Since the three-day rule was adopted, other measures have been put into place to assure that beneficiaries are not inappropriately admitted for SNF care. The Secretary's interpretation of inpatient serves only to deny payment for necessary care, not to ensure appropriateness of care.

As the Court of Appeals noted, CMS is aware that the three-day rule may be outdated. During the course of this litigation, CMS invited public comment on its policy interpretation not to count time spent in observation status towards the three-day stay requirement but then did not change its policy. According to the Court of Appeals, while "CMS's statement with respect to observation status may be less than wholly satisfying, . . . it is not so

deficient that it lacks persuasive force. . . CMS appears to be acutely aware of the changes in medical practice since the 1960s and has declined to include time on observation status because, in its view, doing so would risk undermining congressional intent [that the SNF benefit serve as a less expensive alternative to what would otherwise be the final, convalescent portion of an acute stay of several days as an inpatient at a hospital]." *Landers v. Leavitt*, 545 F.3d at 110.

CMS's decision does "lack persuasive force," *id.*, as it is at odds with the reality of modern medical practice and the underlying purpose of the three-day rule. Appellants' brief thoroughly argues that the Court of Appeals reached erroneous conclusions with regards to the analysis it conducted under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). While *amicus curiae* AARP agrees with these arguments, it seeks to inform the Court about hospital observation units, what the hospital system looked like at the time the Medicare Act was passed, and how and why observation units were developed. Considering the context within which observation units developed and how they actually operate today, AARP urges the Court to recognize that CMS's decision not to cover SNF care of patients who have been in the hospital for at least three days, but as an inpatient for only two, displays invalid, illogical reasoning and is unpersuasive.

ARGUMENT

I. OBSERVATION STATUS WAS DEVELOPED TO SAVE MONEY WHILE CONTINUING TO ALLOW ACCURATE SCREENING OF POTENTIAL ACUTE CARE ADMITTEES.

Patients often enter a hospital through the hospital's emergency room with emergency room stays averaging between two and six hours. Charles Downey, *EDTUs: Last Line of Defense Against Costly Inpatient Stays*, 10 Managed Care Magazine 44 (Apr. 2001), http://www.managedcaremag.com/archives/0104/0104.edtu.html. Before observation units, some patients were quickly treated and released. Others were released after their fears of illness were revealed to be unfounded. Many patients, however, were obviously sick, but the exact causes of their illness, and the appropriate corresponding treatment, could not be determined in a short period of time. These patients were admitted to the hospital and subsequently stayed as inpatients for an average of ten days. *See* Chapin White, *Rehabilitation Therapy In Skilled Nursing Facilities: Effects Of Medicare's New Prospective Payment System*, Health Affairs, 22, 214-223 (2003), *available at* http://content.healthaffairs.org/cgi/content/full/22/3/214 (observing "the drop in average hospital length-of-stay among the elderly from 10.7 days in 1980 to 6.1 days in 1999.") Finally, some patients were erroneously thought to need no further care and discharged to their homes. Some of these patients died needlessly. *See generally* Sean P. Collins, *et al.*, *Cost-effectiveness Analysis of ED*

Decision Making in Patients with Non-high-risk Heart Failure, 27 Amer. J. Emergency Med. 293, 295-96 (2009) (describing how patients who are discharged directly from the ED face risks of early readmission or death ["mirroring in-hospital complications or death had they been admitted"]).

Before observation units were developed, many patients initially admitted as inpatients suffered from illnesses that could be effectively treated in a less-intensive setting at a reduced cost, or only needed intensive treatment for a few additional hours. Other admitted patients, such as those complaining of chest pain, were admitted as inpatients not because they were likely to suffer a heart attack, but because of the unlikely, but horrible, consequences of being released and then subsequently suffering a heart attack. *See* Downey; *supra*, ¶ 21 (quoting the author of a textbook on observation units as stating that 4-5 percent of chest pain patients with severe myocardial infarction or ischemia were not diagnosed correctly, i.e., "missed," and consequently their "morbidity is doubled." He goes on to note that with the advent of emergency room observation units "these misses can nearly be eliminated.")

Similar dynamics are present with asthma patients. Most patients only need short, intensive treatment lasting less than a day, but there are regular but less frequent cases that require more extensive treatment only possibly through inpatient hospitalization. *E.g., see* Enrique Martinez, *et al.*, *The Observation Unit: A New Interface between Inpatient and Outpatient Care*, Am. J. Med., 110,

275-76 (Mar. 2001) (reporting that in one year 83 percent of asthma patients admitted to observation status in Cook County Hospital were discharged home within 23 hours, while the remaining 17 percent required inpatient admission, and that these rates never varied by more than 1 percent in the 3 years covered by the study.)

These examples demonstrate the dilemma. The costs associated with admitting, monitoring, and caring for inpatients were high and growing, and beds in emergency rooms were both expensive to operate and often in short supply. *See* Frederic Platt, *Reviews and Notes: Emergency Medicine: Observation Medicine; and Presenting Signs and Symptoms in the Emergency Department: Evaluation and Treatment*, Annals Internal Med., 120(7) (Apr. 1, 1994) (noting that the best "explanation for the ubiquity of medical observation units is financial. When DRGs came into being, it became economically advantageous for hospitals to label and charge differently their short-stay patients... . But the truth is that a clear and more powerful impetus exists: income available to the health care provider."); *see also* Downey; *supra*, ¶ 2 (observing emergency room visits increased 367 percent from 1955 to 1971). On the other side, the costs of non-treatment could be catastrophic. The solution that emerged was an "observation unit" – a middle-ground station.

The various types of observation units that emerged over time were, and are, so different that to refer to them as units can often be misleading. Broadly speaking, three different types of

observation units exist: 1) emergency observation/treatment units under the control of emergency room personnel where a patient can be treated further or evaluated, 2) holding units which may or may not be under the control of emergency room personnel where patients are housed pending prearranged actions such as admission or transfer, and 3) observation status beds which are beds in the inpatient area, indistinguishable from any other hospital bed, where a patient can be evaluated and/or treated for up to twenty-four hours before a decision on whether to release or admit has to be made. *See* R.M. Coffey, M.L. Barret, & S. Steiner, *Final Report Observation Status Related to Hospital Records*, 8-9, Agency for Healthcare Research & Quality, DHHS (2002), *available at* http://www.hcup-us.ahrq.gov/reports/FinalReportonObservationStatus_v2Final.pdf; *see also* TMF Health Quality Institute, *Medicare Billing Practices: Outpatient Observation vs. Inpatient Admission Patient Guidelines*, *available at:* http://hpmp.tmfhqi.net/LinkClick.aspx?fileticket=zq3tReJ88Ds%3D&tabid=521&mid=1247 (stating "Observation and inpatient are both billing statuses and not locations within the hospital. Some hospitals may have a special area just for observation while others may not.") Experts estimated that as of 2001, 45-50 percent of U.S. emergency rooms also had some form of observation unit. *See* Downey; *supra*, ¶ 13.

Within these varied settings, patients receive intensive, but quick, treatment and then will be released once the alarming symptoms have subsided (e.g., asthma patients). *See* Martinez, *supra*. Or, as already alluded, observation units can also be a

place to monitor and treat patients more cheaply than if they had either continued to take up an emergency room bed or been formally admitted as an inpatient. This was a welcome development since physicians frequently cannot diagnose with any certainty a patient's condition, or order an appropriate treatment, within the first few hours. *E.g.,* Downey, *supra*, ¶ 3 (stating observation units have developed because they "can increase the technical efficiency of hospitals [and] ... improve utilization because 80 percent of patients are found during observation to not have a serious disease and therefore can avoid hospitalization."); *see also* Lee Ann Runy, *Clinical Observation Units*, ¶ 18 (Mar. 2006), http://www.hhnmag.com/hhnmag_app/jsp/articledisplay.jsp?dcrpath=HHNMAG/PubsNewsArticle/data/2006March/0603HHN_FEA_gatefold&domain=HHNMAG (reporting that 25 percent of patients assigned to observation status are subsequently admitted as inpatients.); *see also* Martinez, *supra* (reporting that only 15 percent of patients initially admitted to observation status were subsequently hospitalized as inpatients.) As a result of this development, the medical system was able to reduce expenditures and improve patient outcomes (in some cases, e.g., chest pain, by reducing the number of those erroneously released.) *E.g.,* Michael A. Ross, *Chest Pain Observation Units Reduce Hospital Admission in People with Acute Chest Pain*, 8(4) Evidence-Based Healthcare Mgmt. 180, 180-182 (Aug. 2004) (finding there was little variation in outcomes or subsequent incidence of major events for individuals treated traditionally as inpatients and those who were placed in an observation unit, and that chest pain observation could help mitigate the

$3 billion spent annually on unnecessary admissions).

II. OBSERVATION STATUS OFTEN LENGTHENS THE TIME TAKEN TO DISCOVER HOW ILL PATIENTS ARE AND WHETHER THEY NEED ADDITIONAL CARE.

The role that observation plays today reveals the Court of Appeals' decision to be unconvincing, as it is ultimately based on the notion that CMS cannot change its policy because of a fear that a change "risks undermining Congressional intent to preserve the SNF benefit to those requiring a fairly short intensive stay in a SNF as a continuation of an acute hospital stay of several days." *Landers v. Leavitt*, 545 F.3d at 109. There may be valid reasons to initially assign a patient to observation status instead of ordering an admission; but there is no reason to treat patients assigned to observation status for one day and confirmed to need the intensive services associated with inpatient status for two additional days (a total of three days in the hospital), differently than those who spend all three days in the hospital as an inpatient.

For example, a patient arriving at the emergency room with chest pain is often quickly admitted to observation status to monitor and determine if a heart attack is imminent. Because most patients are not in such danger, determining this before they are admitted can save the hospital and CMS money. But some are in danger, and once this has been determined, these patients are

admitted as inpatients. It is not that the patient was somehow not as sick or did not need attention while she was in observation status. Instead, the hospital system has been re-engineered over time to allow this sorting mechanism to take place over a longer period of time at a lower overall cost. But patients who are admitted as inpatients right away, and a patient who is admitted to observation status for one day, confirmed to need intensive services, and then receives them over two days as an inpatient are essentially the same – patients in need of intensive services. As these are the persons Congress intended to cover in the original Medicare Act, the fact that medical practice now takes longer to sort patients into categories of (crudely speaking) the "very sick" in need of hospitalization and those "not-so-sick" who can be released, but does so more accurately and at less cost to society, should not be reason to arbitrarily deny SNF benefits to some subset of the "very sick" just because the system now takes longer to identify them.

In short, one principle function of observation status is most accurately perceived as a filtering function - a function that previously took place *as an inpatient*, but which is now done while in observation status at a lesser total cost. Regardless, anyone who spends three days in the hospital is quite obviously ill and in need of serious medical attention.

The Court of Appeals' finding that CMS decision (to define inpatient as requiring formal admission to a hospital) is justified because it advances Congressional intent to target the SNF

benefit to, apparently, the "sickest," echoes the District Court's rationale that those patients immediately admitted to inpatient status and who stay hospitalized for three days "could reasonably be expected to have more serious health problems, and thus a greater need for post-hospital SNF care, than patients whom medical service providers adjudge as not requiring such extended care in the hospital." *Landers v. Leavitt*, 2006 WL 2560297 at *9 (D. Conn. Sept.1, 2006). The error is that patients who are admitted as inpatients for at least three days *should not be compared* to patients who can be released within twenty-four hours. Petitioner and AARP do not argue that patients assigned to observation status and released within twenty-four hours should be eligible for SNF coverage, instead they argue that CMS has not identified any well-reasoned, substantiated or logical reasons as to why, in terms of post-hospital care, the fates of patients assigned to observation status, but subsequently transferred to inpatient status as their physician recognizes the severity of their illness, should be treated any differently from patients whom physicians recognize as needing inpatient services immediately.

III. OBSERVATION STATUS IS OFTEN USED AS A DEFAULT OPTION FOR BILLING PURPOSES SINCE THE PATIENT CAN RECEIVE THE SAME MEDICAL SERVICES HE OR SHE WOULD HAVE RECEIVED AS AN INPATIENT.

The objective differences between observation and inpatient status are minimal. A subset of

patients in "observation" are assigned to such a status not because the physician thinks the patient can be released within twenty-four hours, but because the physician suspects the patient should be admitted, but does not yet have enough documented information to enable such a decision to withstand the scrutiny of those who decide reimbursement matters. *See* TMF Health Quality Institute, *Medicare Patients: Observation or Inpatient Admission?*, http://www.hcpro.com/content/222633.pdf (providing a flow-chart to guide providers in decision-making relating to admissions. The chart instructs practitioners to err on the side of observation status when uncertainty remains). *Amicus curiae* suggests that this subset accounts for a disproportionate number of patients who are initially assigned to observation, but subsequently formally admitted (e.g., the plaintiffs in this case). And although physicians ostensibly employ objective medical criteria to decide whether to admit to observation or as an inpatient, once assigned a status, the patient frequently receives no different medical treatment. *See generally* Wyatt Decker, *et al.*, *A Prospective, Randomized Trial of an Emergency Department Observation Unit for Acute Onset Atrial Fibrillation*, 52 Annals of Emergency Med. 322 (Oct. 2008) (comparing differences between emergency department observation unit protocols and those employed in routine hospital admission and management. The study concluded, "An ED observation unit protocol . . . is a feasible alternative to routine hospital admission for acute onset of atrial fibrillation and results in a shorter initial length of stay").

Physicians are instructed to use observation status in this manner by a "decision-tree" guide that was produced by the TMF Health Quality Institute *under a contract with* CMS. *See* TMF Health Quality Institute, *Medicare Patients: Observation or Inpatient Admission?*, http://www.hcpro.com/content/222633.pdf ("Using outpatient observation as an alternative to admission will allow you time to determine if admission is necessary, reduce denials for unnecessary admissions and ensure that some payment is received for services rendered.")

Various publications reinforce the fact that the difference between observation and inpatient status is a billing distinction, because the medical treatment a patient receives is not different. One publication explains "the distinction between inpatient and extended outpatient observation represents a difference in billing, not a difference in medical treatment. The distinction is medically irrelevant to the ordering physician, and therefore is frequently not addressed explicitly." Administrative Consultant Services, LLC, *Bed*, I(VII), 5 & 8 (Jun. 1, 2006), *available at* http://www.acsteam.net/newsletters/medob0606.pdf. One CMS fiscal intermediary frankly states in a Local Coverage Determination (LCD), "Although in many institutions there is no difference between the actual medical services provided in inpatient and observation settings, in such cases the designation still serves to assign patients to an appropriate billing category." Riverbend Government Benefits Administrator, *LCD for Acute Care: Inpatient, Observation and Treatment Room Services (L1281)*,

¶ 2, http://www.rgbagov.com/publications/lcd/lcd-files/1281b.html.

Another CMS contractor (Lumetra, the CMS-designated Quality Improvement Organization for the state of California) makes this point more obliquely when it states that observation status is the appropriate choice when "Your patient can be evaluated or treated within 24 hours. *If you are unsure, select Observation Care*," parroting a popular "decision guide" designed to help doctors correctly chose between inpatient and observation status. Lumetra, *Hospital Observation Versus Inpatient Admission: Time to Get Your Questions Answered*, 6 (Jul. 17, 2006) (emphasis in original), *available at* http://www.lumetra.com/uploadedFiles/events/recorded-events/2006-08-08-observation-vs.-admission.pdf.

The decision guide cited by Lumetra makes two important points. First, doctors are instructed to use observation status if they think they will be able to *evaluate* a patient within 24-hours. This supports the assertion that the current observation status is frequently just a way station along the path to inpatient status, a way station that did not exist when the Medicare statute was passed because "observation" units/status did not yet exist. Previously, this evaluation was most likely performed after a patient had been formally admitted. Second, in the event that a physician is uncertain as to whether a patient should be admitted, they are instructed to choose observation status as the default. It is important to note that physicians will frequently choose observation status

if any uncertainty exists as to reimbursement for their services. *See* TMF Health Quality Institute, *TMF Review & HPMP Update*, 1 (Dec. 2004), *available at* http://www.tmf.org/update/archive/1204Update.pdf ("Handling care in outpatient observation when appropriate ... reduces denials for unnecessary admissions *and ensures that some payment is received.* The care can be the same as care provided to an inpatient, but how that care is reimbursed is different—*outpatient observation is strictly a billing status.*") (emphasis added)

Since the care a patient receives is frequently no different whether in observation or inpatient status, basing the decision of whether to cover post-hospital SNF care on location simply does not make sense. In addition, CMS, through decision guides produced and promulgated by its contractors, instructs physicians to resolve any uncertainty in favor of observation status. *See* Lumetra, *supra*. CMS's definition of "inpatient" is presumably valid because it leaves the decision to the supposedly objective, "medical judgment" that ostensibly lies behind a physician's decision to admit as an inpatient or into observation. Reality is that placing a patient in observation is as likely a result of a lack of a bed, a lack of diagnostic accuracy, or a concern for billing as it is a product of objective medical decision making. *See* TMF Health Quality Institute, *Review Related Frequently Asked Questions*, ¶¶ 11-13, http://casereview.tmf.org/ReviewRelatedFAQs/tabid/506/Default.aspx (admitting that TMF would interpret a physician's written order to "admit *to* observation" differently from "admit *for* observation," with the former being interpreted as observation

status, while the latter is deigned an inpatient, implicitly acknowledging that the coverage of a patient's SNF care hinges upon a doctor's (perhaps careless) choice of a preposition.)

CONCLUSION

For the foregoing reasons, this Court should grant petitioners' writ of certiorari.

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